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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,504	10/26/2001	Yi-Ren Woo	1416.03US01	4675

22865 7590 09/12/2003

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EXAMINER

SWEET, THOMAS

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/004,504

Applicant(s)

KIM, HYUN-HO

Examiner

Thomas J Sweet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 24-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to an implantable prosthesis with filler in pores, classified in class 623, subclass 11.11.
- II. Claims 24-38, drawn to a heart valve with pores, classified in class 623, subclass 2.2.
- III. Claim 39, drawn to a method of making an implant, classified in class 216, subclass 41.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because claim 24 does not claim a filler. The subcombination has separate utility such as tissue implant.

Inventions III and I or II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case) the product as claimed can be made by another and materially different process,

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such as molding. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Hallie Finucane on 9/2/03 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-23. Affirmation of this election must be made by applicant in replying to this Office action. Claims 24-38 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-2, 4-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Li et al (US 6231879). Li et al discloses an implantable prosthesis (title) comprising a rigid material (col 8, lines 16-17) with pores filled with hydrogel (col 8, lines 5-15) and a structural protein (collagen, col 6, lines 43-57).

With regard to claim 4, the collagen is only coated in the pores

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With regard to claims 9-11 and 13, See column 1, lines 14-20 and column 10, lines 39-65.

With regard to claim 14, see column 7, lines 1-4.

With regard to claims 16 and 17, the material is an open celled foam having a network of pores (col 5, lines 46-54)

With regard to claim 18, collagen is a nutrient.

With regard to claim 19, seeded with cells (col 14, lines 1-2).

With regard to claims 20 and 21, see column 3-4, lines 64-5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5-15, and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor (US 4936317) in view of Carlyle et al (WO 01/41825). MacGregor discloses a heart valve (col 3-6) including a rigid polymer occluder with a porous surface. However, MacGregor does not disclose a filler consisting of mixtures of hydrogel, structural protein and bioactive agents. Carlyle et al discloses a coating for heart valves occluders consisting of mixtures of hydrogel, structural protein and bioactive agents for the purpose of causing cell adhesion to the surface. It would have been obvious to one of ordinary skill in the art at the time

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the invention was made to coat the occluder of MacGregor with the coating material of Carlyle et al (thereby filling the pores of the occluder) in order to promote cell adhesion to the surface.

With regard to claim 3, the surface in figures of Carlyle et al appears smooth and page 3 states that it is suitable for contact with the patients bodily fluids.

With regard to claim 5, see page 12, 2nd paragraph of Carlyle et al.

With regard to claims 6 and 7, see page 7, 2nd paragraph of Carlyle et al.

With regard to claim 8, see page 22, 2nd paragraph of Carlyle et al.

With regard to claims 9-13, see page 7, 2nd paragraph of Carlyle et al.

With regard to claim 15, both of Carlyle et al and MacGregor mention the use of anticoagulants. However, the filler as disclosed does not include anticoagulant. It is well known in the art of hydrogels to include anticoagulants therein to prevent clotting. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include anticoagulant in the hydrogel of Carlyle in order to prevent clotting.

With regard to claim 18, collagen is a nutrient of Carlyle et al.

With regard to claim 19, see page 25, 2nd paragraph of Carlyle et al.

With regard to claims 20-21, see page 12, 1st paragraph of Carlyle et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas J Sweet whose telephone number is (703) 308-4018.

The examiner can normally be reached on 6:30 am - 5:00pm, M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M McDermott can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

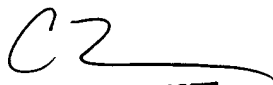
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

tjs


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TECHNOLOGY CENTER 3700